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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): GUID.119PA

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on July 30, 2007

Signature: Tracey M. Dotter

Typed or printed name: Tracey M. Dotter

Application Number	Filed
10/821,125	4/8/2004

First Named Inventor: Favet

Art Unit	Examiner
3766	Malamud, D

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [X] attorney or agent of record. Registration number 38,491
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Mark A. Hollingsworth
Typed or printed name

952-854-2700
Telephone number

July 30, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[X] *Total of 1 forms are submitted.

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	Favet et al.	Examiner:	Malamud, D.
Serial No.:	10/821,125	Group Art Unit:	3766
Filed:	April 8, 2004	Docket No.:	GUID.119PA
Title:	MINIMALLY PROGRAMMABLE ICD WITH ASYSTOLE PREVENTION		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this Transmittal Letter and the papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 30, 2007.

By: Tracey M. Dotter
Tracey M. Dotter

APPELLANT'S STATEMENT IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This statement is presented in compliance with the USPTO OG Notice of 12 July 2005 on New Pre-Appeal Brief Conference Pilot Program. Appellant requests a pre-appeal brief conference on the belief that the rejections of record are clearly not proper and without basis. Appellant's request is based upon a clear legal or factual deficiency in the rejections, rather than an interpretation of the claims or the prior art teachings. As such, Appellant believes this request for pre-appeal brief review is appropriate.

Claims 1-12 each stand rejected under 35 U.S.C. §102(b) based upon U.S. Patent No. 5,074,301 to *Gill* (hereinafter "*Gill*"). Claims 13-15 and 68 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Gill*.

While Appellant would present multiple issues on appeal, the purpose for submitting this request for review primarily concerns the §102(b) rejection of independent claim 1, which is insufficiently supported by the teachings of *Gill*. Specifically, Appellant notes that *Gill* does not provide any teachings corresponding to

Appellant's claimed non-physiologic, life sustaining pacing therapy. The Examiner appears to take the untenable position that any pacing therapy, including *Gill's* bradycardia therapy, constitutes a non-physiologic, life sustaining pacing therapy.

Appellant's independent claim 1 recites, among other features, control circuitry provided in the housing and coupled to the energy delivery circuitry and the detection circuitry, the control circuitry configured to coordinate delivery of the tachyarrhythmia therapy in response to detection of a tachyarrhythmia requiring treatment and delivery of the non-physiologic, life sustaining pacing therapy in response to detection of cardiac asystole.

Gill discloses an implantable medical device to detect ventricular tachycardia and ventricular fibrillation and "deliver therapy in the form of electrical energy to cardiac tissue to revert tachycardia and restore sinus rhythm." (Col. 1, Lines 8-12). *Gill* acknowledges that the heart may be stopped after delivery of cardioversion therapy. (Col. 6, Lines 34-37; Fig. 4C). Therefore, *Gill's* device delivers bradycardia pacing therapy after the delivery of cardioversion therapy and detection of asystole as part of *Gill's* therapy regime to restore sinus rhythm. (Col. 6, Lines 34-39; Fig. 4C). Appellant respectfully submits that *Gill's* teaching of delivering bradycardia pacing to treat asystole and restore sinus rhythm does not constitute an anticipatory teaching of a non-physiologic, life sustaining pacing therapy.

Bradycardia pacing therapy, as understood by one having ordinary skill in the art, paces a heart faster than the intrinsic rate to increase cardiac output and support physiologic function of a patient. For example, although *Gill* does not explicitly define bradycardia pacing, *Gill* does discuss "a bradycardia support system as well as a high energy shock system to revert ventricular tachycardia to normal sinus rhythm." (Col. 1, Line 68 – Col. 2, Line 2; emphasis added). *Gill's* invention delivers a high energy shock followed by bradycardia pacing to restore sinus rhythm. (Col. 1, Lines 9-12; Fig. 4C).

As quoted in MPEP § 2131, "the identical invention must be shown in as complete detail as is contained in the ... claim." (*Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Appellant respectfully submits that *Gill* does not disclose delivery of a non-physiologic, life sustaining pacing therapy, as recited in independent claim 1. Nothing from *Gill's* disclosure teaches that

Gill's bradycardia pacing is anything but conventional bradycardia pacing that supports cardiac output to restore physiologic function.

Furthermore, not only does *Gill* fail to disclose a non-physiologic, life sustaining pacing therapy, but *Gill's* disclosure of a bradycardia therapy diverges from a teaching of a non-physiologic, life sustaining pacing therapy, such that the two therapies would be understood to be materially different by one having ordinary skill in the art.

For example, the differences between non-physiologic, life sustaining pacing therapy and bradycardia pacing therapy are highlighted by the Specification as follows:

> An implantable cardiac device of the present invention finds particular utility in the context of preventing sudden cardiac death (SCD) in patients that may not require a traditional implantable cardiac defibrillator (ICD). Although ICDs are very effective at preventing SCD, most people at risk of SCD are not provided with implantable defibrillators. Many people that are at risk of SCD, for example, may not have a history of arrhythmias or other comorbidities that are often considered threshold factors that must be present before a person can receive an ICD. The high costs of conventional ICDs (device and surgical implant costs), and the relatively stringent requirements that a candidate patient must satisfy in order to justify the risks and costs of conventional ICD implantation, may also significantly limit the number of patients that can receive a conventional ICD. Other reasons why people at risk of SCD do not receive conventional ICDs, particularly those that have a cardiac pacing capability, include the limited number of physicians qualified to perform lead/electrode implantation and pacing threshold determinations, and a limited number of surgical facilities adequately equipped to accommodate such cardiac device implant procedures. Each year, SCD claims the lives of some 300,000 Americans—with 80% to 90% of those deaths caused by ventricular fibrillation.
>
> It is believed that an implantable cardiac device of the present invention may be appropriate for implantation in a significantly larger patient population than that for which conventional ICDs are appropriate.
> [Page 7, Line 10 – Page 8, Line 3]
>
> . . .
>
> Embodiments of the present invention are directed to maintaining circulatory support by providing post-shock pacing pulses from an SCDP device. Embodiments of the present invention are directed to post-shock asystole prevention using post-shock pacing therapies. According to one approach, and <u>in contrast to conventional bradycardia pacing modalities, normal heart rate is not maintained by the SCDP device</u>. Rather, a single pacing pulse is delivered after a predetermined interval following detection of the last R-wave or delivery of a pace pulse (i.e., asystole detection). Delivery of post-shock pacing pulses is terminated once the heart is able to beat on its.
> [Page 28, Lines 15-23; emphasis added]

Furthermore, Appellant's Specification identifies a "non-physiologic, life sustaining pacing therapy" as pacing at a rate lower than bradycardia pacing. ("[i]n an embodiment in which asystole prevention pacing is also made available, the SCDP device 502 produces pacing pulses in accordance with a non-physiologic, life sustaining pacing therapy, such as pacing therapy deliverable at a rate lower than a bradycardia pacing rate." Specification, Page 20, Lines 15-18).

Appellant is well aware that limitations from the Specification are not read into the claims. However, Appellant notes that reference to the Specification to understand claim terms is well known as an acceptable means to highlight difference between the claims and prior art. (See *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)). Identifying portions of the Specification to show that bradycardia therapy and a non-physiologic, life sustaining pacing therapy are different therapies with different parameters is not improperly importing a limitation into the Specification. Moreover, the independent claims already recite "non-physiologic," and as such Appellant is not importing limitations into the claims.

Appellant respectfully submits that Appellant's claimed invention and *Gill's* conventional bradycardia therapy device address different problems with materially different therapies. This distinction illustrates that *Gill's* bradycardia pacing therapy and Appellant's non-physiologic, life sustaining pacing therapy are clearly different therapies, and that *Gill's* bradycardia pacing therapy does not anticipate a non-physiologic, life sustaining pacing therapy, as recited in independent claim 1.

Moreover, the Examiner has recognized differences in therapies during the course of prosecution of this case that clearly require recognition that bradycardia pacing and a non-physiologic, life sustaining pacing therapy are materially different. For example, when addressing the restriction requirement applied by the Examiner, the Examiner stated that the "non-physiologic, life sustaining pacing therapy" of claim 1 is a "different therapy strategy, in response to a different, more specific cardiac condition than" the "pacing therapy deliverable at a rate lower than a bradycardia pacing rate" of claim 16. (Office Action mailed 3/28/2007, Page 3). The above statement was made in the Office Action even though Appellant pointed out on page 14 of the response filed 1/25/2007 that

the Specification states that a pacing therapy deliverable at a rate lower than a bradycardia pacing rate is a non-physiologic, life sustaining pacing therapy.

Therefore, the sustaining rational for the restriction recognized a difference between a non-physiologic, life sustaining pacing therapy and a pacing therapy deliverable at a rate lower than a bradycardia pacing rate that makes the two therapies recognizable as different therapies. Even if there is a difference between those two therapies, the difference is small, particularly in comparison to the far greater differences between *Gill's* bradycardia therapy that restores normal sinus rhythm and a non-physiologic, life sustaining pacing therapy of claim 1. As such, the sustaining rational for the restriction requirement demands that *Gill's* bradycardia therapy and a non-physiologic, life sustaining pacing therapy of claim 1 be recognized as materially different therapies.

For each of the reasons discussed above, Appellant respectfully submits that claim 1 recites features that must be given patentable weight and, when properly given such, clearly distinguish the elements and limitations of independent claim 1 from *Gill's* disclosure. Consequently there is an omission of at least one essential element required for a proper anticipation rejection of independent claim 1. Claims 2-12 that depend from claim 1 are also not anticipated by *Gill*. Claims 13-15 and 68 are patentable over *Gill* for at least the reason that these claims depend from patentable claim 1 and that all elements of claims 13-15 and 68 are not taught or suggested by *Gill*, for reasons discussed hereinabove and in Appellant's prior responses.

The undersigned is of record and with authority to prosecute the appeal on behalf of the Assignee.

Respectfully submitted,

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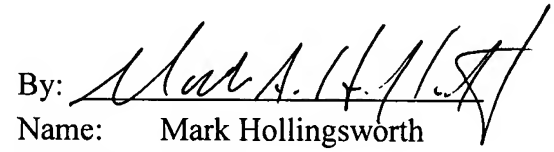
By: 
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